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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/879,329	06/12/2001	Ethan R. Signer	408445	4053

23557 7590 10/15/2004

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[REDACTED] EXAMINER

SULLIVAN, DANIEL M

[REDACTED] ART UNIT 1636 PAPER NUMBER

DATE MAILED: 10/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/879,329	SIGNER ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Daniel M Sullivan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 02 August 2004.

2a) This action is **FINAL**.                    2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1, 4, 6, 10, 12, 14, 15, 17 and 18 is/are rejected.

7) Claim(s) 2,3,5,7-9,11,13,16,19 and 20 is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_

4)  Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_

5)  Notice of Informal Patent Application (PTO-152)

6)  Other: \_\_\_\_\_

**DETAILED ACTION**

This Office Action is a reply to the Paper filed 2 August 2004 in reply to the Non-Final Office Action mailed 1 April 2004. Claims 1-20 were considered in the 1 April Office Action. Claims 1, 18 and 20 were amended in the 2 August Paper. Claims 1-20 are pending and under consideration.

***Response to Amendments***

**Claim Rejections - 35 USC § 112**

Rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

**Claim Rejections - 35 USC § 102**

Claims 1 and 4 stand rejected under 35 U.S.C. 102(e) as being anticipated by Bauer *et al.* U.S. Patent No. 6,534,315 for reasons of record and herein below in the response to arguments.

**Claim Rejections - 35 USC § 103**

Claims 1, 6, 10, 12, 14 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* (*supra*) for reasons of record and herein below in the response to arguments.

Claims 1, 4, 17 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* as applied to claims 1 and 4 above and further in view of Ow, D. (WO 93/01283) for reasons of record and herein below in the response to arguments.

### ***Response to Arguments***

Claims 1 and 4 are rejected under 35 U.S.C. 102(e) as being anticipated by Bauer *et al.* In response, Applicant has amended the claims such that the direct repeats of a gene of interest are capable of recombination with the genome of the host cells and are immediately flanking the positive and negative selectable marker gene. Applicant argues that the claims are now distinguished from the teachings of Bauer *et al.* because Bauer teaches that the direct repeat sequences are non-recombinogenic with the genome of the host strain. Applicant urges, “the DRSs in Bauer must be non recombinogenic; *i.e.*, these sequences are designed so that they do not recombine with the genome of the host cells...By contrast, the DRSs that are presently claimed are direct repeats of the gene of interest, and can mediate the integration of the entire DNA construct into the host genome by recombination” (page 5 of the 2 August Paper).

These arguments have been fully considered but are not deemed persuasive. Although the DRSs of Bauer *et al.* are designed such that they do not mediate homologous recombination, the DRSs are DNA, and like all DNAs are “capable of recombination”. It is clear from the teachings of Bauer *et al.*, viewed as a whole, that non-recombinogenic does not mean incapable of recombination, which is inconsistent with the nature of DNA. It should be noted that Bauer *et al.* teaches that the DRS sequences can be “yeast DNA sequences not present in the host strain” (column 6, line 51). Thus, Bauer *et al.* teaches that the DRSs can be heterologous genes that are

heterologous to the host cell genome, which is precisely what is comprised by the construct of the instant claims and provides the “random insertion mediated by the presently claimed DRSs” (2 August Paper, bridging pages 5-6).

Applicant argues that in Bauer *et al.*, the DRS is non-coding while the DRS in the present claims “can be coding”. This argument is not persuasive because although it is acknowledged that Bauer *et al.* teaches that the DRS should be non-coding, the DRS of the present claims is not limited to being a coding sequence. In fact, paragraph [0031] of the instant application teaches, “A ‘gene of interest’ or ‘GI’ and the ‘additional genes’ or ‘AG’ include, but are not limited to, genes which are not normally present in the transformed plant. This includes DNA sequences not normally transcribed into RNA or translated into a protein (expressed), or any other genes or DNA sequences which one desires to introduce into the non-transformed plant.” Thus, viewed in light of the specification, the DRSs of the claimed genetic construct can comprise any DNA sequence which one desires to introduce.

Applicant points out that Bauer *et al.* teaches that the construct should comprise recombinogenic sequences which correspond to the desired insertion in yeast while the RSs in Bauer *et al.* mediate insertion of the DNA cassette into the host genome through homologous recombination. Again, Applicant appears to be reading limitations into the claims. As shown in the Exhibit I filed with the 2 August Paper, the construct of Bauer *et al.* comprises direct repeat sequences flanking positive and negative selectable markers, which are capable of recombination (although designed so as not to provide homologous recombination) and which meet the broad definition of a gene of interest as set forth in the specification. Given that the instant genetic construct is open (*i.e.*, “comprises” the various elements set forth) and not limited to not

comprising sequence that is homologous to the host cell genome, the fact that the construct of Bauer *et al.* further comprises “recombinogenic sequence” does not distinguish the claims from the teachings of Bauer *et al.*

Finally, Applicant argues that, in contrast to the construct of Bauer *et al.*, according to the present claims, only one copy of the gene of interest is left on the host chromosome after successful integration/excision. Applicant cites paragraph [0021] as supporting this contention. However, the only statement regarding the gene of interest in paragraph [0021] reads, “[t]he subject invention also provides compositions comprising genetic constructs that provide at least one gene of interest and at least two selectable marker genes and a carrier.” Again it is noted that the present constructs are claimed using open language and, contrary to Applicants assertion, are not limited to providing only one copy of the gene of interest on the host chromosome. The constructs of Bauer *et al.* comprise each of the structural limitations of the claimed constructs and, therefore, would function in the same way.

Applicant’s arguments have been fully considered but are not deemed persuasive either individually or as a whole; therefore, the claims stand rejected under 35 U.S.C. §102(e) as being anticipated by Bauer *et al.*

#### Claim Rejections - 35 USC § 103

Claims 1, 6, 10, 12, 14 and 15 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.*

In response to the *prima facie* case of record, Applicant traverses the rejection on the grounds that there is no suggestion or motivation in Bauer *et al.* or in the knowledge generally

available to one of ordinary skill to modify the constructs and methods taught by Bauer *et al.* Applicant's position appears to be based on the allegation that the differences between the construct taught by Bauer *et al.* and the construct of the instant claims are more extensive than the order of the positive and negative selectable marker genes comprised within the construct. However, for the reasons provided herein above, the instant claims are not so limited as to be distinguished from the construct of Bauer *et al.* in any way other than the order of the positive and negative selectable marker genes. Applicant appears to be reading limitations into the instant claims based on the differences in the intended use of the instant constructs relative to the constructs of Bauer *et al.* and based on the presence of additional elements in the construct of Bauer *et al.* However, the relevant inquiry is not whether the preferred embodiment of the invention is different from what is disclosed by the art, but whether the art teaches an embodiment that falls within the scope of the claim. For the reasons provided above, Bauer *et al.* teaches a construct comprising each of the limitations of the construct of the instant claims except for stating a specific order of the positive and negative selectable marker genes. As stated in the previous Office Action, “*a prima facie* case of obviousness may be made when chemical compounds have very close structural similarities and similar utilities because one skilled in the art would be motivated by the expectation that compounds of similar structure will have similar function (see *e.g.*, MPEP 2144.09). Thus, it would be *prima facie* obvious to the skilled artisan to use either of the configurations of positive and negative selectable markers set forth in the claims.”

Applicant's arguments have been fully considered but are not deemed persuasive either individually or as whole; therefore, the claims stand rejected as obvious over Bauer *et al.*

Claims 1, 4, 17 and 18 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Bauer *et al.* as applied to claims 1 and 4 above and further in view of Ow.

Applicant traverses the rejection on the grounds set forth herein above regarding obviousness and anticipation of the claims by Bauer *et al.* These arguments are not deemed persuasive for the reasons set forth herein above.

***Allowable Subject Matter***

Claims 2, 3, 5, 7-9, 11, 13, 16, 19 and 20 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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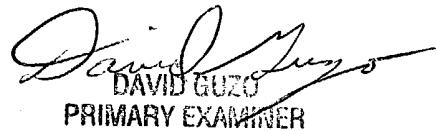
however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Daniel M Sullivan, Ph.D.  
Examiner  
Art Unit 1636



DAVID GUZIO  
PRIMARY EXAMINER